



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| | | | | |
|---|-------------|----------------------|---------------------------------------|------------------|
| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/657,725 | 09/08/2003 | Louis C. Smith | AVSI-0010 P1 (108328.0015) | 8903 |
| 25555 7590 03/15/2007 JACKSON WALKER LLP 901 MAIN STREET SUITE 6000 DALLAS, TX 75202-3797 | | | EXAMINER WILLIAMS, CATHERINE SERKE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3763 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
| 3 MONTHS | | 03/15/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/657,725 | SMITH ET AL. | |
| | Examiner | Art Unit | |
| | Catherine S. Williams | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 20-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____. |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/31/05;5/19/05;9/13/04;8/18/04.

Art Unit: 3763

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 12/18/06 is acknowledged.

Claims 20-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 12/18/06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 11-13 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubinsky et al (USPN 6,387,671). Rubinsky discloses an electrode assembly having a plurality of needle electrodes; a current waveform generator; a power source and a controller. See figure 7; 4:38-57; 10:44-45, 52; 11:20-36; 13:45-63; and 14:26-34, 59-63.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3763

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubinsky.

Rubinsky meets the claim limitations as described above but fails to disclose a communications port specifically an optical serial port or an infrared port. However, wireless communication is well known in the medical device art in general and is provided in order to make use of the device easier for the patient and medical technician.

At the time of the invention, it would have been obvious to incorporate an optical serial port or an IR port into the invention of Rubinsky. These devices are well known in the art and the motivation for the incorporation would have been known generally by one skilled in the art. The incorporation would have been done in order to make the use of the device easier for the patient and medical technician thereby enhancing the device in general.

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubinsky in view of Hofmann (USPN 5,318,514). Rubinsky meets the claim limitations as described above but fails to disclose that the electrode assembly has a handle with a mounting structure and an activation switch. Hofmann clearly discloses a handle (24) with a mounting structure (see figure 3) and an activation switch (34).

At the time of the invention it would have been obvious to incorporate the handle of Hofman into the invention of Rubinasky. Rubinsky fails to disclose a specific structure for the needle electrode assembly. The motivation for the incorporation of the handle of Hofmann into

Art Unit: 3763

the invention of Rubinsky would have been done in order to carry out the device and method as taught by Rubinsky.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubinsky in view of Hofmann. Rubinsky in view of Hofmann meets the claim limitations as described above but fails to include a LED on the handle. LEDs are well known in the medical device art as status indicators that indicate to the medical technician if a device is powered on or off.

At the time of the invention, it would have been obvious by one skilled in the art to incorporate an LED into the handle. The motivation for the incorporation would have been done in order to make the device easier to use for the medical technician.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rubinsky in view of Hofmann et al (USPN 5,702,359). Rubinsky meets the claim limitations as described above (see claim 1) but fails to disclose that the plurality of needle electrodes have a central channel. However, Hofmann discloses such a configuration with at least some of the needles having lumens for drug delivery. Hofmann discloses that this configuration is for enhanced performance of the device.

At the time of the invention, it would have been obvious by one skilled in the art to use the electrode array of Hofmann in the device of Rubinsky. Rubinsky fails to disclose a specific structure for the needle electrode assembly. The motivation for the incorporation of the electrode assembly of Hofmann into the invention of Rubinsky would have been done in order to carry out the device and method as taught by Rubinsky with the enhanced design of Hofmann.

Art Unit: 3763

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571/2724970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571/2724977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Catherine S. Williams
March 7, 2007

CATHERINE S. WILLIAMS
PRIMARY EXAMINER